

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5500.2
Revision 3

11/17/08

SIGNIFICANT INCIDENT RESPONSE

I. PURPOSE

This directive outlines the procedures that the Emergency Management Committee (EMC) is to follow while managing significant incidents that may adversely impact food security and public health.

Key Points:

- *renames the Non Routine Incident Management System (NRIMS) to FSIS Incident Management System (FIMS), incorporates information on utilizing FIMS to track and manage significant incidents and clarifies the definitions of alerts and significant incidents*
- *provides instructions for completing, and information on accessing, FSIS Form 5500-4, Incident Report (IR)*
- *provides instructions for FSIS Form 5500-8, Impact of Significant Incidents on Establishments, Warehouses and Import Houses*

II. CANCELLATION

FSIS Directive 5500.2, Revision 2, Non-Routine Incident Response, 4/9/08

III. REASON FOR REISSUANCE

This directive is being reissued in its entirety primarily to establish a more descriptive terminology for significant incidents that may adversely impact food security or public health and for the system that will be used to manage them. The Non-Routine Incident Management System (NRIMS) will be renamed the FSIS Incident Management System (FIMS) and the term “non-routine incident” will be replaced by “significant incident”. This directive is also being reissued to establish the use of the FIMS for sending alerts of foodborne investigations and to clarify email notification procedures.

IV. REFERENCES

9 CFR Part 300 to end

V. BACKGROUND

A. A significant incident presents a grave or potentially grave threat to public health involving FSIS-regulated product or to food security. Examples of significant incidents include but are not limited to the following:

1. life-threatening human illnesses potentially implicating FSIS-regulated product that lead to a foodborne incident investigation;
2. Class I recalls resulting from one or more illnesses involving FSIS-regulated product;
3. deliberate contamination of FSIS-regulated product;
4. threat condition Orange or Red with a specific threat to the food and agricultural sector;
5. animal disease with potentially significant public health implications for FSIS-regulated product;
6. ineligible foreign product in the United States (U.S.) where there is a reasonable probability that the consumption of the product will pose a serious health hazard;
7. high risk products in the U.S. as identified by Customs and Border Protection; and
8. suspicious activities observed or made known (e.g. bomb threats, etc.) by program personnel while performing their normal duties.

B. Additional situations that FSIS may consider to be significant incidents include:

1. natural disasters (e.g., hurricanes, floods, tornadoes, earthquakes);
2. terrorist attacks on the nation's critical infrastructures;
3. other incidents requiring a national coordinated response that result in the activation of the Emergency Support Function -11 (ESF-11) at the FEMA National Response Coordination Center, which is described in the Agriculture and Natural Resources Annex to the National Response Framework; and

4. incidents involving FSIS-regulated products and law enforcement or other regulatory agencies for which a coordinated response may be necessary, as well as significant unanticipated expenditure of FSIS resources, e.g., stolen trucks or excessive levels of chemical residues.

VI. AGENCY PERSONNEL RESPONSIBILITIES FOR REPORTING A SIGNIFICANT INCIDENT

A. Agency personnel are to immediately report any potential significant incident as defined in Section V (A) through supervisory channels. The information reported, at a minimum, is to include:

1. the name of the person who reported the incident;
2. date and time of the incident;
3. location of the incident;
4. the type of threat, hazard, or disease;
5. the type of product involved, and
6. number of reported illnesses and deaths (if applicable).

B. Designated personnel with access to FIMS will review the incident information and, if appropriate, develop the Incident Report (IR) and enter the report into FIMS.

C. For Class I recalls involving one or more illnesses (Section V, 2 of this directive), Office of Public Affairs and Consumer Education (OPACE) will initiate the IR in FIMS and post the recall release.

D. For all incidents that involve law enforcement agencies or the need to notify OIG, the Office of Program Evaluation, Enforcement, and Review (OPEER) must be notified via e-mail by the reporting program office.

1. The electronic IR form can be accessed through FIMS via the following intranet link: <http://FIMS.fsis.usda.gov>

2. The electronic IR in the FIMS automatically saves the IR as its case number. The case number is derived using the following: year, month, day, number of IR entered that day, e.g., 20070130-01 means this is the first IR in 2007 reported on Jan. 30.

3. All approved IRs in FIMS are automatically forwarded to the AA or designee of the Office of Food Defense and Emergency Response (OFDER) and the originating program area's Assistant Administrator (AA), or their designees, for review following the automated process outlined in Attachment 1. EMC members on duty also will get a

copy.

4. Program offices are to update the IR as often as necessary through FIMS. The most recent information will appear first on the IR. Whenever the IR is updated, an e-mail notification will be sent to all EMC members on duty.

VII. FIMS OR E-MAIL SYSTEM OUTAGE

A. In the event that the FIMS system is non-operational, the person who generates the IR should send the information to the OFDER AA or designee and their respective area AA or designee as an attachment to an e-mail or via fax.

B. In the event that the e-mail system is non-operational, the person who generates the IR is to send a PIN, via personal digital assistant (e.g., Blackberry), to the OFDER AA and to his/her own AA. The two AAs will review the information and make a determination regarding the IR in accordance with this directive.

C. In the event that both systems are non-operational, the person who generates the IR is to verbally notify his/her EMC representative. The EMC representative will provide further communication instructions at that time.

D. When the FIMS system becomes operational, the person who initiated the IR during the outage is to enter the information into FIMS.

VIII. REVIEW OF THE IR

A. The OFDER AA and the AA responsible for the IR, or their designees, will review the submitted IR and, as appropriate, decide:

1. that no action is required at this time;
2. to alert the EMC; or
3. to activate the EMC.

B. The OFDER AA and the AA responsible for the IR will determine further actions that will be taken on the open IR. An IR is closed when the incident that caused the report is resolved. An IR is archived when it is determined that the incident will take an extended period of time to resolve such as a pending criminal investigation. Once the investigation is complete the IR will move from archived to closed.

C. An IR can be classified as "restricted" when it contains sensitive information that is not to be shared with all FIMS users.

D. If the OFDER AA and the AA responsible for the IR determine that the incident may warrant further discussion by the EMC, FIMS will send a notification (alert) to the EMC representatives. This notification alerts the EMC representatives that there is a significant incident that may warrant EMC activation. The alert notification will include information on how and when the discussion will take place.

E. If the OFDER AA and the AA responsible for the IR determine that the EMC needs to be activated, FIMS will send an e-mail, a phone message, or both to the EMC representatives on duty for each program area. The message will provide instructions on where to convene or how to participate in a conference call. The FSIS Management Council, the Office of the Under Secretary for Food Safety, the Office of the Administrator, and the USDA Homeland Security Office will be provided a copy of the notification for alerts and activations.

F. An alert will be sent through FIMS when a foodborne illness investigation is initiated as per Directive 8080.3. The Foodborne Disease Investigations Branch (FDIB) Chief will determine whether FDIB should issue an alert through FIMS to inform other FSIS program areas or the EMC of the investigation. Alerts provide early notification of investigations that will likely necessitate Agency action or commitment of resources.

NOTE: Situations that are likely to justify the above Agency action are detailed in FSIS Directive 8080.3 Sec. VIII.

IX. EMERGENCY MANAGEMENT COMMITTEE (EMC)

A. The EMC is comprised of senior management personnel (AA or designee) from each of the FSIS program offices. Each program office EMC representative has the authority to commit, as necessary, the resources of his or her respective program office in responding to the incident. The EMC duty roster is available in FIMS and also is issued via email weekly to all program areas. The list contains on-call members and contact information for each program area.

B. The EMC may be alerted or activated at any time, on any day of the year, to address and manage the Agency's response to a significant incident involving potentially-adulterated or adulterated FSIS-regulated product. The EMC can also be activated if the Recall Committee is unable to reach consensus on whether the Agency should request that a company conduct a recall. In the event the incident does not result in adulteration of FSIS-regulated product, the purpose of the EMC activation would be to determine how to work with other involved agencies, to assign responsibilities for any information gathering, and to decide how best to provide the public with information about the safety of the product.

C. The AA or the EMC representative from OFDER serves as the Incident Commander (IC). The IC coordinates the work of the EMC in response to a particular significant incident. Depending on the nature, scope, and complexity of the incident, the IC may designate any member of the EMC as IC to coordinate key activities critical to

the management of the incident.

D. OFDER maintains an up-to-date roster of on-call EMC members, including home, work, and cell/Blackberry phone numbers, PINs, and e-mail addresses. OFDER develops emergency incident reports (e.g., IRs, Situation Reports when the ESF-11 is activated or when requested by the Department) and monitors related intelligence. OFDER maintains the FSIS Situation Room and Agency preparedness plans in conjunction with the Department's Continuity of Operations Plans (COOP). In conjunction with the Department's Homeland Security Office, OFDER is FSIS' emergency incident liaison with other Federal agencies.

X. THE WORK OF THE EMC

A. Upon alert or activation, the EMC evaluates the information provided on the IR and determines what further information is needed to complete the assessment of the significant incident. The EMC also develops and implements an incident action plan, the execution of which is monitored by the IC through FIMS.

B. The EMC coordinates the development of responses to questions about the incident, including responses to questions about illness prevention, hazard detection, incident containment, and remediation. The EMC also recommends Agency actions to detect and mitigate the hazard that caused the incident, including the formation of an Incident Investigation Team (see FSIS Directive 5500.3) to investigate matters such as why FSIS regulated product is causing illnesses.

C. The IC provides progress reports to the FSIS Management Council (i.e., Office of the Administrator and AAs) as requested. All program areas are to routinely provide updates through FIMS to assist the IC in tracking the incident response, reporting progress, and maintaining relevant documents and a chronology of events.

D. When the incident has been resolved, the IC, in conjunction with the EMC members, will deactivate the EMC and advise the Administrator and FSIS Management Council. All EMC representatives and other parties will be notified through FIMS, and the IR will be closed.

XI. COMPLETING FSIS FORM 5500-8 IMPACT OF SIGNIFICANT INCIDENTS ON ESTABLISHMENTS, WAREHOUSES, AND IMPORT ESTABLISHMENTS

A. Agency personnel complete FSIS Form 5500-8 to collect and submit information about the operational status of official establishments, facilities that handle FSIS-regulated products (e.g., large warehouses), and import facilities affected by a significant incident such as an earthquake, flooding, fire, or hurricane.

NOTE: The form can be accessed through FIMS at <http://FIMS.fsis.usda.gov>, in Outlook Public Folders\All Public Folders\Agency Issuances\Forms\5000 Series and

also in inside FSIS <http://inside.fsis.usda.gov> for those individuals without access to FIMS.

B. OFDER will notify the appropriate EMC representatives to collect information about the operational status of establishments or facilities within their jurisdiction.

C. The EMC representative will then notify the appropriate personnel within his or her program, for example, the District Manager (DM), Import Inspection Division's (IID) Deputy Director for Operations (DDO), or the Compliance Investigation Division (CID) Regional Manager (RM), to collect the information and complete FSIS Form 5500-8, available through FIMS. FSIS field personnel may be requested to supply information on whether official establishments or facilities are operational as a result of the significant incident so that the District Manager, Regional Manager or the DDO can complete the form in FIMS.

D. To complete the 5500-8, the DM, DDO, RM, or their designees may need to contact other personnel such as Front-line Supervisors, Consumer Safety Officers, Enforcement, Investigations, and Analysis Officers, Compliance Investigators, Regional Import Field Officers, Import Surveillance and Liaison Officers, or Import Inspectors. The following information is needed to complete the 5500-8:

1. the official identification numbers for non-operational establishments or facilities in OFO's or OIA's areas of responsibility;

2. the addresses of non-operational high volume distribution points (e.g., wholesale grocery suppliers or transportation centers) in OPEER's area of responsibility; and

3. the reason why the establishment or facility is not operational:

- a. no establishment or facility personnel present;
- b. damage from flooding;
- c. building destroyed;
- d. no electricity; or
- e. other (specify).

E. The DM, DDO, RM, or their designees will complete FSIS Form 5500-8 in FIMS.

F. After the initial submission of a completed FSIS Form 5500-8, the DM, DDO, RM, or their designees will notify OFDER through FIMS each time there is a change in a facility's operational status. This notification should be provided no later than at the close of business each day. Daily updates are not needed if there is no change in

status. OFDER will attach the 5500-8 to the IR.

XII. ANALYSIS OF INFORMATION

The information collected about significant incidents in FIMS, including operational status of establishments, will be evaluated and analyzed by OFDER. Results of the analysis will be used to inform new or existing data initiatives and develop enhanced capabilities of FIMS to effectively manage significant incidents.

Direct questions through supervisory channels.

A handwritten signature in black ink, appearing to read "Theresa S. Duffin".

Assistant Administrator
Office of Policy and Program Development

IR Process Via the FIMS Based on Incident Information

Program Area	Incident Information Sources	FSIS Personnel with Access to the FIMS for IR Development	FSIS Personnel Responsible for IR Review	FSIS Personnel Responsible for Approving IR	FIMS Dissemination of IR
OA	External Federal Agencies	OFDER - Recorder	OFDER – AA or designee	OFDER – AA or designee	OFDER AA/EMC reps
OFDER	OA External Agencies Other Program Offices	OFDER - Recorder	AA or designee	AA or designee	AA/EMC Rep
OIA	Field & External Agencies IES IEPS IAS IID	IES Director IEPS Director IAS Director IID Director	IES Director IEPS Director IAS Director	IES Director IEPS Director IAS Director * *cc: DAA, Directors: IES, IEPS, IID, IAS	OIA AA OFDER AA
	Foreign Governments	Deputy Director Import (IID) Operations	Directors: IES,IEPS, IAS, IID	Directors: IES, IEPS, IAS * *cc: DAA, Directors: IES, IEP, IID, IAS	OIA AA OFDER AA
	External - (Others) Field ISLOs	Deputy Director Policy Deputy Director Operations	Director IID	Director- IID* *cc: DAA, Directors: IES, IEPS, IID, IAS	OIA AA OFDER AA

Program Area	Incident Information Sources	FSIS Personnel with Access to the FIMS for IR Development	FSIS Personnel Responsible for IR Review	FSIS Personnel Responsible for Approving IR	FIMS Dissemination of IR
OPEER	External Agencies or CID	Deputy Director, Compliance Specialist, Regional Manager, Supervisory Compliance Investigator, Sr. Compliance Investigator, Compliance Investigator	Regional Manager	Regional Manager* *cc: CID Director	OPEER AA OFDER AA
	ICAD Federal State Programs	Director ICS	Director ICAD	Director ICAD	OPEER AA OFDER AA
OPACE	Hot Line Information	Hot Line Specialist and Manager	FSES Director	OPHS/HHSD Director	OPHS AA OFDER AA
	External Sources	Director: ECIMS, CPAO, FSES	Director: ECIMS, CPAO, FSES	OPACE AA	OPACE AA OFDER AA
OFO	External Agencies IICs FLS	District Manager or designee, DDM, Case Specialist, District Analyst, Director RMD or designee	District Manager or designee	District Manager or designee	OFO AA OFDER AA
OPPD	IICs Industry FLS	Director: PDD, PAD, LPDD	OFO District Manager	OFO District Manager	OFO AA OFDER AA

Program Area	Incident Information Sources	FSIS Personnel with Access to the FIMS for IR Development	FSIS Personnel Responsible for IR Review	FSIS Personnel Responsible for Approving IR	FIMS Dissemination of IR
OPHS	External Agencies, State and Local Partners, PHEIs, CCMS FDIB illness investigation	AED Director Or designee CCMS staff FDIB Branch Chief PHEIs	AED Director Or designee	AED Director Or designee	OPHS AA OFDER AA
	Laboratories, CDC Liaison	OPHS AA Lab Directors	OPHS AA	OPHS AA	OPHS AA OFDER AA
OOEET	Regional Trainers and Field personnel	OOEET AA Outreach and Partnership Division Staff	OOEET AA or designee	OOEET	OOEET AA OFDER AA
OM	Field Personnel (FPC, Urbandale, IA & HRFO, Minneapolis MN); Field Safety and Health (SH) Specialists	OM AA & DAA; OCHCO & Deputy Division Directors & Deputies; CFO & Deputy; EHSB Chief; SH Specialists	OM AA/DAA or designee	OM AA/DAA or designee	OM AA OFDER AA